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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,224	08/23/2001	Peter Samuel James Cheetham	Mewburn	1819

7590 11/06/2002
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EXAMINER

HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,224

Applicant(s)

CHEETHAM ET AL.

Examiner

Keith Hendricks

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,14-20,24-28 and 30-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-13,21-23 and 29 is/are rejected.
- 7) ☐ Claim(s) 6, 8 and 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-3, 6-13, 21-23 and 29, in Paper No. 8 is acknowledged.

Response to Amendment

The preliminary amendment to the claims filed on 8-31-01 does not comply with the requirements of 37 CFR 1.121(c) because the amendment to claim 3, last line, involving the term "favours", appears as "favo[u]rs". It is agreed that the term should be spelled "favors", however, as the "clean copy" of the claim contains brackets reserved for the amended copy, a new clean copy of the claim is required to be submitted by applicant in the next response.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 29 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to a strain of microorganism which exists in nature; thus the claim is directed to a product of nature, without a human 'inventive step' involved. It is suggested that, at the least, the claim be amended to recite that the microorganism is "isolated" and/or "purified", if supported by the specification.

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Claim Rejections - 35 USC § 112

i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 2 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The deposit of the microorganism has not met the requirements under this statute. The pertinent passages are highlighted in **bold**, below, including means to overcome the rejection.

Since the *Pseudomonas putida* IMI382568 microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and **it is not clear from the specification or record that the microorganism is readily available to the public.**

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. **If the depository is made under the terms of the Budapest Treaty (see pages 9-10 of the instant specification), then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.**

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,
- (d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,7,10-13 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for the phrase "the vanillin accumulates". It is unclear where this accumulation occurs, either in the cell or as excreted into the culture medium. Further, although not necessary to recite in the instant claims, this would also affect subsequent steps, which would differ depending upon the collection methods necessary.

Claim 7 recites a closed group as "selected from"; however, this does not comply with accepted U.S. patent language necessary to clearly define the metes and bounds of the claim. It is suggested that the claim be amended to "selected from the group consisting of".

Claim 10 is indefinite, as it is unclear if this recited temperature range is in Celsius or Fahrenheit degrees.

Claim 11 is indefinite for the recitation of the term "involves". It is unclear if this step "consists of" heating in water (i.e. closed language), or "comprises" heating in water (i.e. open language).

Claim 12 is indefinite for the recitation of the phrase "derived from a species of *Aspergillus* or *Humicola insolens*." *Humicola insolens* is a single species, and thus the enzyme may not be "derived from a species of *Humicola insolens*." It is suggested that the term "from" be inserted before the name *Humicola insolens* in the claim, or that the entire phrase be rearranged to recite "derived from *Humicola insolens* or a species of *Aspergillus*."

Claim 13 is indefinite for the phrase "effected substantially." The metes and bounds of the phrase are indefinite, as it is unclear as to how a treatment may be "substantially" effected, but not effected. Alternatively, the phrase "substantially in the pH range 6-7" is also indefinite, as it is unclear as to what pH values outside of the range 6-7 would be included or excluded in the claim.

Claim 21 is indefinite for the recitation of the phrase "said at least one desired component." This lacks a clear antecedent basis within the claim, and within claim 1, from which it depends.

Claim 22 is suggested to clarify that the subject of the phrase "a strain of microorganism", is *Pseudomonas putida*.

Claim 22 is indefinite, as the screening protocol described therein does not clearly set forth positive method steps, such that the purpose and steps of the claim are clear to one skilled in the art. "Screening... by means of a reagent suitable for detecting aldehydes" does not set forth what is actually done or accomplished by the method, whether this is a positive or negative selection, or how this relates to the microorganism(s) sought.

Claim 23 is indefinite for the recitation of the phrase "obtained by mutation." The colonies do not appear to be "obtained by" mutation, in the sense that this would be how the inventors "obtained" the

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colonies. Further, this phrase does not clearly set forth how it relates to the claimed invention, and how one skilled in the art would reproduce the steps. The nexus between the claim and the claim(s) from which it depends, is unclear.

Claims 22-23 do not appear to properly correspond to claim 1, from which they depend. Reference to the specification, at example 4 and at pages 42-47, describes the circumstances under which the screening for aldehyde production is performed. These are not stated to be applicable to (a) *Pseudomonas putida*, or (b) to the production of vanillin from ferulic acid. There is no clear nexus for this method protocol and the production of vanillin from ferulic acid using *Pseudomonas putida*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 21-23 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Labuda et al. (US PAT 5,279,950).

Labuda et al. disclose a method of converting ferulic acid to vanillin, comprising treating a composition comprising ferulic acid with a strain of *Pseudomonas putida* (examples 1 and 4) under conditions of pH and temperature necessary to promote the production and accumulation of vanillin. See columns 5-6 and 8, regarding the yield and accumulation of vanillin. Column 6, lines 54-64, and column 7, describes the extraction and analysis of the vanillin compound from the mixture using organic phase separation techniques (reverse phase HPLC). The HPLC analysis utilizes an apparatus and reagent "suitable for detecting aldehydes", as was done by applicant at example 16. The colonies of microorganisms were mutated through natural selection, thus meeting the limitations of claim 23.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: Claims 6-9 and 10-13 are free of the prior art of record. From a prior art perspective, these claims appear to possess some or all of the combined elements of Labuda et al., as cited above, and Myers et al. (WO 96/39859,

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provided to applicant in the International examination). However, there is no motivation present in the teachings of the prior art to combine these two teachings for the production of vanillin from the recited plant materials, as presently claimed. Claims 7-8 and 10-13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

NOTE: The references listed in the International Search Report, to the extent that they have been made available to the Office, have been considered with regard to patentability of the instant elected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



**KEITH HENDRICKS
PRIMARY EXAMINER**